IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

American Academy of Pediatrics, *et al.*, Plaintiffs, v. **Food and Drug Administration**, *et al.*, Defendants.	Case No. PWG-18-883

STATUS REPORT

In accordance with the Court's revised remedial order (ECF No. 202), Defendants respectfully report as follows:

1. **Covered Applications:** This report includes information about "Covered Applications" as defined in paragraph 7 of the Court's revised remedial order. The FDA has used the same method for determining which applications constitute Covered Applications as it did in its previous status reports (ECF Nos. 205, 207, 209). Defendants conferred with Plaintiffs, who agreed that the set of applications covered by paragraph 7 of the revised remedial order is the same as in the previous status reports.[1]

2. **Overall Progress:** The FDA remains committed to completing review of the applications it has received as soon as feasible to protect and promote the public health. As of December 31, 2022, the FDA had taken action on 51% of Covered Applications. The FDA

[1] The FDA initially identified 240 applications as "Covered Applications," but the agency since determined that it had inadvertently included seven applications for products that were not on the market as of August 8, 2016, and thus do not constitute Covered Applications under the revised remedial order. *See* ECF No. 202 ¶¶ 1, 7. Accordingly, there are 233 Covered Applications. All estimates in this status report reflect this correction.

reports the following revised estimates, which represent the FDA's best forecast based on current information. Overall, the FDA expects to have taken action on:

52% of Covered Applications by March 31, 2023;

53% of Covered Applications by June 30, 2023;

55% of Covered Applications by September 30, 2023; and

100% of Covered Applications by December 31, 2023.

These revisions reflect the many challenges the FDA faces issuing marketing decisions related to e-cigarette products. Specifically, JUUL, Logic, NJOY, and Fontem have each separately sued the FDA in federal courts of appeals challenging the agency's decisions on their Covered Applications. Since September 2021, the FDA has seen more than 50 lawsuits challenging its e-cigarette marketing decisions. Defending those lawsuits and undertaking multiple related application re-reviews continues to require substantial agency resources. The FDA's revised projections also reflect the fact that, for some pending Covered Applications, the agency has received amendments that it has accepted and is considering, pursuant to 21 C.F.R. § 1114.9.

Despite these challenges, FDA has taken action on over 99% of the nearly 6.7 million deemed products for which applications were submitted by this Court's September 9, 2020 deadline. This includes action on 72% of the Covered Applications for non-tobacco-flavored e-cigarette products and over 61% of the Covered Applications from the four largest brands. *See* Richard Craver, *Reynolds' Vuse e-cigarette widens market-share lead over Juul*, Winston-Salem Journal (Jun. 2, 2022), available at https://journalnow.com/business/local/reynolds-vuse-e-cigarette-widens-market-share-lead-over-juul/article_50c7c64c-e0f1-11ec-a069-b354b0aad375.html (identifying Vuse, Juul, NJOY, and blu (Fontem) as the top four in terms of

market share). The FDA's actions also include issuing marketing denial orders today for two Vuse menthol e-cigarette products.

3. In accordance with the revised remedial order, the FDA will file another status report by April 24, 2023, reporting any revisions to its estimates.

Dated: January 24, 2023

Respectfully submitted,

Of counsel:

SAMUEL R. BAGENSTOS
General Counsel
U.S. Dep't of Health and Human Services

MARK RAZA
Chief Counsel
United States Food and Drug Administration

WENDY S. VICENTE
Deputy Chief Counsel for Litigation

JONATHAN SILBERMAN
Associate Chief Counsel

Office of the Chief Counsel
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

BRIAN D. NETTER
Deputy Assistant Attorney General

ERIC B. BECKENHAUER
Assistant Branch Director

/s/ Garrett Coyle
GARRETT COYLE (Bar No. 809812)
Trial Attorney
U.S. Department of Justice
Civil Division, Federal Programs Branch
1100 L Street NW
Washington, DC 20005
Phone: (202) 616-8016
Fax: (202) 616-8470
garrett.coyle@usdoj.gov

Counsel for Defendants